

2. REMARKS / DISCUSSION OF ISSUES

Claims 1-19 are pending in the application. Claims 1 and 12 are the independent claims.

Rejections under 35 U.S.C. §101

1. Claims 1-11 were rejected under 35 U.S.C. §101 as allegedly not falling into one of four statutory categories of invention. The Office Action asserts that “based on consideration of all relevant factors with respect to the claim as a whole, claim 1 is held to claim an abstract idea, and is therefore ineligible subject matter under 35 USC 101.” Applicants respectfully disagree.

35 U.S.C. §101 recites:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

Claim 1 recites:

A method of capturing an image using an ultrasound system, comprising:
directing ultrasound waves from the ultrasound system to a body;
surveying the image to collect motion data;
analyzing the motion data to identify a flow in the image, the analyzing
comprising segmenting the image into a flow region and a non-flow region;
scanning a limited region of the image containing the flow with a flow imaging
technique;
distinguishing plaque from clutter when low-level echoes are present; and
adjusting a gain of an image acquisition system based on whether plaque is
present or clutter is present in the image.

So, claim 1 likely falls under the statutory category of a process under 35 U.S.C. §101. Without basis in law, the Office Action relegates the claim, as a whole, to being an

abstract idea, and specifically as allegedly being mental human activity. Applicants respectfully disagree.

Notably, capturing of an image using an ultrasound system cannot be implemented via human mental activity. Nor can the directing of ultrasound waves; or the surveying of the image to collect motion data. The analyzing of the motion data comprises segmenting the image into flow and non-flow regions. This segmentation system is not disclosed as being implemented in other than hardware, or software, or both, using the ultrasound system 10, for example in the filed application. As such, Applicants respectfully submit that as a whole, claim 1 is directed not to an abstract idea that can be carried out only through human mental activity, but rather to a process that can be implemented using hardware or software, or both. As such, claims 1-11 are directed to statutory subject matter, and the rejection under 35 U.S.C. § 101 is improper and should be withdrawn.

2. Claims 12-19 were rejected under 35 U.S.C. § 101 as allegedly not falling into one of four statutory categories of invention. Notably, the Office Action asserts that claim 12 “lacks definite structure indicative of a physical apparatus.” No basis in law to support the assertion is presented in the Office Action.

Claim 12 recites:

An ultrasound system stored in a computer readable medium, comprising:

a survey system for collecting motion data from a target image;

an image acquisition system;

a segmentation system for mapping a region of flow within the image based on the motion data, the segmentation system configured to segment the image into a flow region and a non-flow region;

a flow acquisition system that automatically limits the collection of flow image data within the image to the region of flow; and

a plaque/clutter analysis system configured to distinguish between plaque and clutter and to adjust a gain of the image acquisition system based on whether plaque is

present or clutter is present.

Applicants respectfully submit that the ultrasound system of claim 12 is “functional descriptive material,” because it “consists of data structures and computer programs which impart functionality when employed as a computer component.” *See, e.g.*, MPEP § 2106.01. Moreover, “[w]hen functional descriptive material is recorded on some computer-readable medium, it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. *See, e.g.*, MPEP § 2106.01. Accordingly, Applicants submit that claim 1 is directed to statutory subject matter, and thus respectfully request withdrawal of the rejection under 35 U.S.C. § 101.

Rejections under 35 U.S.C. § 103

Claims 1-19 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over *Hatfield, et al.* (U.S. Patent 5,840,032), *Lin, et al.* (U.S. Patent 5,957,138) and *Muzilla, et al.* (U.S. Patent 6,500,125). For at least the reasons set forth below, Applicants respectfully submit that all claims are patentable over the applied art.

A *prima facie* case of obviousness has three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, requires some reason that the skilled artisan would modify a reference or to combine references.¹ The Supreme Court has, however, cautioned against the use of “rigid and mandatory formulas” particularly with regards to finding reasons prompting a person of ordinary skill in the art to combine elements in the way the claimed new invention does.² But rather the Supreme Court suggests a broad, flexible “functional approach” to the obviousness analysis recognizing that “[i]n many fields it may be that

¹ See *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332 (Fed. Cir. 2005) (“[S]imply identifying all of the elements in a claim in the prior art does not render a claim obvious.”).

² See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007) (“The obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents.”).

there is little discussion of obvious techniques or combinations.”³ Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the same time the invention was made. In other words, a hindsight analysis is not allowed.⁴ Lastly, the prior art reference or combination of references must teach or suggest all the limitations of the claims.⁵

i. Claims 1 and 12:

Claim 12 recites:

An ultrasound system stored in a computer readable medium, comprising:

a survey system for collecting motion data from a target image;

an image acquisition system;

a segmentation system for mapping a region of flow within the image based on the motion data, the segmentation system configured to segment the image into a flow region and a non-flow region;

a flow acquisition system that automatically limits the collection of flow image data within the image to the region of flow; and

*a plaque/clutter analysis system configured to distinguish between plaque and clutter and to **adjust a gain of the image acquisition system based on whether plaque is present or clutter is present.***

Claim 1, which is directed to a method, includes similar features to those emphasized in claim 12 above.

The Office Action directs Applicants to *Lin, et al.* for the alleged disclosure of the plaque/clutter analysis system set forth in claim 12. While Applicants in no way concede

³ *Id.* See also *Id.* at 1743 F. 3d 1356 (Fed. Cir. 2006) (“Our suggestion test is in actuality quite flexible and not only permits, but *requires*, consideration of common knowledge and common sense”) (emphasis in original).

⁴ See *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991) (“Hindsight is not a justifiable basis on which to find that ultimate achievement of a long sought and difficult scientific goal was obvious.”).

⁵ See *In re Wilson*, 424 F.2d 1382 (C.C.P.A. 1970) (“All words in a claim must be considered in judging the patentability of that claim against the prior art.”).

this assertion, a review of *Lin, et al.* fails to uncover the disclosure of adjusting the gain of an image acquisition system based on whether plaque or clutter is present. Rather, *Lin, et al.* merely discloses that plaque may be viewed.

For at least the reasons set forth above, Applicants respectfully submit that the applied art fails to disclose at least one feature of each of claims 1 and 12. Therefore, assuming arguendo but not conceding the propriety of the combination of *Hatfield, et al.*, *Lin, et al.*, and *Muzilla, et al.*, Applicants respectfully submit that a *prima facie* case of obviousness cannot be established based thereon. Accordingly, claims 1 and 12 are patentable over the applied art. Moreover, claims 2-11 and 13-19, which depend immediately or ultimately from claims 1 and 12, respectively, are patentable for at least the same reasons and in view of their additionally recited subject matter.

Conclusion

In view of the foregoing, applicant(s) respectfully request(s) that the Examiner withdraw the objection(s) and/or rejection(s) of record, allow all the pending claims, and find the application in condition for allowance.

If any points remain in issue that may best be resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted on behalf of:
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